DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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STATEMENT OF

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FOOD AND DRUG ADMINISTRATION

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON ENERGY AND COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

JULY 17, 2007

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, Chairman Stupak and Members of the Subcommittee. I am Dr. Andrew von Eschenbach, Commissioner of Food and Drugs at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). I am pleased to be joined here today by my Agency colleagues Dr. Robert Brackett, Director of the Center for Food Safety and Applied Nutrition (CFSAN), Ms. Margaret Glavin, Associate Commissioner for Regulatory Affairs, and Mr. Stephen Mason, Acting Assistant Commissioner for Legislation. We appreciate the opportunity to discuss FDA's food safety activities and the transformation initiative underway in FDA's Office of Regulatory Affairs (ORA), which will enhance FDA's ability to prevent and respond to food safety problems.

In my testimony today, I will describe FDA's role in food safety and some of the efforts we have underway to help prevent future outbreaks. I will also describe how ORA's proposed transformation will support and enhance our food safety programs.

The Office of Management and Budget (OMB) and the relevant food safety agencies are collaborating on ways to most effectively address issues raised in the General Accountability Office's (GAO) designation of Federal Oversight of Food Safety as a high-risk item in February 2007.

FDA is committed to ensuring that America's food supply continues to be among the safest in the world. In recent years, we have done a great deal to protect the food supply from both unintentional and deliberate contamination. We have made significant progress, but the 2006

and 2007 outbreaks of foodborne illness in humans due to contaminated fresh produce and peanut butter and the illnesses in pets due to contaminated animal food, as well as the problem of potentially harmful drug residues in farm-raised Chinese seafood, underscore the need to develop new multidisciplinary and integrated food safety strategies at FDA. These new strategies are necessary to meet the challenges created by changes in the global food supply; changes in farming, manufacturing, and processing practices; and changes in consumer demographics and needs.

Because I am committed to ensuring that the U.S. food supply remains safe and secure, I recently created the new position of Assistant Commissioner for Food Protection. I have appointed Dr. David Acheson to that position. Dr. Acheson's first priority is to develop a new strategy for food safety and food defense that will address changes in the global food safety and defense system, identify our most critical needs, and serve as a framework to help us address the challenges we face. Our goal is to augment our current comprehensive and robust food protection program in a way that is tailored to meet the risks posed by the types of foods we regulate. I expect the plan to focus on efforts by industry to prevent food problems, and FDA interventions that provide the tools and science necessary not only to head off outbreaks of foodborne illness but address intentional contamination as well, and also to ensure compliance with preventive controls that are designed to stop problems before they arise. The result should be a stronger preventive national food protection infrastructure capable of rapid response when contaminated food or feed is detected, or when there is harm to human or animal health.

Although the outbreaks since last summer presented challenges to FDA, they also demonstrated FDA's ability to respond quickly and effectively to protect consumers. Upon becoming aware

of a foodborne illness outbreak associated with FDA-regulated products, FDA's Emergency Operations Center (EOC) coordinates the Agency response, providing a central point in the Agency for managing the early phases of an emergency so that crucial information can be shared and acted upon immediately by appropriate FDA offices. This enables FDA to initiate investigations quickly; often the same day as developing information is obtained. The EOC coordination also enables FDA to base public health messages on real-time up-to-date information. It provides technical experts within FDA with access to both investigational and analytical data to facilitate their ongoing evaluations with the goal of making appropriate recommendations to prevent further illness and adverse impact to human and animal health. EOC staff are available on an around-the-clock basis. As appropriate, FDA works closely with our sister public health agency in HHS—the Centers for Disease Control and Prevention (CDC)—the states, and other agencies, in any emergency response.

During last fall's foodborne illness outbreak of *Escherichia coli* (*E. coli)* O157:H7 associated with fresh spinach, FDA investigators were in spinach processing facilities in California the day after CDC notified us of the outbreak. Similarly, when CDC informed FDA of a multi-state outbreak of *Salmonella tennessee* apparently associated with Peter Pan peanut butter, FDA sent investigators into the ConAgra peanut butter plant the next day. The Agency warned consumers the day after CDC notified us of these outbreaks. When Menu Foods, a pet food manufacturer, notified FDA that it was conducting a recall of certain pet food due to illnesses and deaths of cats and dogs, FDA initiated an inspection of the Menu Foods manufacturing facility the next day and notified consumers within 48 hours.

Although FDA has demonstrated its ability to respond quickly to protect public health, the outbreaks have shown that a great deal more needs to be done to enhance prevention of problems at the source.

FDA'S ROLE IN FOOD SAFETY

FDA's mission is to promote and protect the public health. Ensuring that FDA-regulated products are safe and secure is a vital part of that mission. FDA is the Federal agency that regulates everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at the United States Department of Agriculture (USDA).

Although FDA has the lead responsibility within HHS for ensuring the safety of food products, CDC has an important complementary and non-regulatory public health role. CDC is the lead Federal agency for conducting disease surveillance and outbreak investigations and routinely monitors the occurrence of specific illnesses in the U.S. attributable to contaminated foods within the food supply. The disease surveillance systems coordinated by CDC, in collaboration with states, provide an essential early-information network to detect and minimize the impact of foodborne illness outbreaks.

In addition to working closely with CDC, FDA has many other food safety partners – Federal, state, and local agencies; international food safety partners; consumers, academia; and industry.

FOOD SAFETY FROM FARM TO FORK

To reduce the risk of foodborne illness at all points in the food chain, FDA has adopted a "farm-to-fork" approach to food safety. This approach systematically applies risk management principles at each step as food moves from growers and producers to consumers.

FDA has focused its food safety efforts in three key areas:

- strengthening the scientific basis for FDA's food safety program with a focus on prevention;
- enhancing effective partnerships, both domestic and international; and
- improving risk-based targeting of inspection resources.

I will elaborate on these below.

Strengthening the Scientific Base for FDA's Program to Improve Food Safety

Improving the effectiveness of FDA's food safety program requires strengthening the science base that supports FDA's food protection work. FDA's food safety science program involves a number of intramural and extramural efforts, which can play a major role in reducing levels of foodborne illness. For example, FDA has conducted research focused on: (1) identifying mechanisms of contamination of fresh produce with pathogens and preventing contamination; (2) identifying effective interventions to address contamination that has occurred; and (3) developing fast and sensitive analytical methods for the detection of pathogens on fresh produce. The results of FDA's research help the Agency develop, implement, and evaluate policies designed to improve food safety. They also help maintain FDA's awareness of emerging issues and enable the Agency to respond rapidly to emergencies.

Extramural collaborations allow FDA to make its resources go further and use those resources more efficiently to address food-related safety concerns, and to prepare for new and emerging issues. For example, for the past decade, FDA has worked closely with USDA's Agricultural Research Service (ARS) and Cooperative State Research, Education, and Extension Service (CSREES) to coordinate and mutually support our respective science efforts related to produce safety. This relationship allows FDA to augment its resources and scientific laboratory expertise. During the outbreak of illness associated with spinach last fall, we were able to capitalize on that ongoing relationship by collaborating with ARS and CSREES to analyze water samples from the Salinas watershed for *E. coli* O157:H7 and to relate the location of bacteria to geographical, seasonal, or rainfall variation. An extension of this research will look for sources of *E. coli* O157:H7 in California's Salinas Valley. As part of our plan to be more proactive about food safety, we will use information obtained from this study to inform produce growers about strategies to prevent pre-harvest microbial contamination.

We strengthen the scientific base for our program through collaborations and also by participating in many scientific and technical meetings on food safety. In February, for example, we participated in a forum sponsored by the Western Institute for Food Safety and Security to share information on assessing industry approaches to address the safety of lettuce and leafy greens on the farm and at packing, cooling, and processing facilities. Also in February, the FDA-affiliated Joint Institute for Food Safety and Applied Nutrition and the University of Florida sponsored a workshop to improve understanding of how tomatoes become contaminated with *Salmonella* and other pathogens. And on May 30 and 31, FDA, the National Center for Food Safety and Technology, and the University of Georgia's Center for Food Safety

co-sponsored a workshop on microbial testing to reach a consensus on the role of microbial testing to ensure the safety of produce.

In response to the recent outbreaks associated with fresh produce, FDA held two public hearings on March 20 and April 13 of this year. The purpose of these hearings was for FDA to share information about the recent outbreaks of foodborne illness related to fresh produce and to solicit comments, data, and additional scientific information on this issue. We are soliciting input from all our stakeholders on ways to improve the safety of fresh produce and the Agency is currently evaluating the comments we received in response to these hearings.

Enhancing Effective Partnerships

To succeed in our science-based efforts to promote food safety, we need to enhance our collaborations with stakeholders interested in food safety. For example, fresh produce is produced on tens of thousands of farms, and contamination at one step in the growing and processing chain can be amplified at the next step. One of the key elements of FDA's 2004 Produce Safety Action Plan calls for efforts to improve communication and collaboration with all our food safety stakeholders. FDA has worked with the public and private sector to encourage industry to follow the recommendations and standards contained in FDA guidance documents. After enlisting the help of the scientific community and the industry, FDA published the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This guide, published in 1998, recommends good agricultural practices and good manufacturing practices which growers, packers, and shippers can take to address common risk factors in their operations. FDA and USDA issued the guidance in several languages and have

conducted significant outreach, both domestically and internationally, to encourage its implementation. In addition, FDA has assisted industry in developing a number of commodity-specific food safety guidelines for the commodities most often associated with foodborne illness outbreaks. These include guidelines for lettuce and leafy greens, melons, and tomatoes. Industry is currently working on similar guidance for herbs and green onions, for which FDA is providing technical input.

The following example of fresh alfalfa sprouts illustrates how successful these efforts can be. In 1999, there were 390 reported illnesses associated with eating contaminated fresh sprouts. FDA published two guidance documents for sprouts that year. In 2004, only 33 illnesses were reported associated with fresh sprouts and, in 2005 and 2006, there were none. We believe that the subsequent decline in sprout-associated illnesses was in large part due to the industry's adherence to the recommendations FDA provided in those guidance documents through our outreach, inspection, and sampling efforts. In addition, maintaining this low incidence requires FDA's continued outreach and industry vigilance. Although no set of actions can be expected to prevent all outbreaks, we believe that adherence to this guidance will likewise reduce the risk of future outbreaks.

FDA's efforts in this area are ongoing. In March, FDA issued a draft final version of its "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" (the Fresh-cut Guide). This guidance is intended for all fresh-cut produce firms, including, among others, those that process fresh-cut spinach and lettuce/leafy greens, to enhance the safety of fresh-cut produce by minimizing the microbial food safety hazards. In addition, because food safety is truly an international public health issue, the FDA-led Delegation of the United States to the

Codex Committee on Food Hygiene spear-headed the request from the Codex Alimentarius Commission (the international food safety standards body) to the Food and Agriculture Organization/World Health Organization (FAO/WHO) for an expert consultation on the microbiological safety of fresh produce to support the development of commodity-specific annexes to the hygienic code. FAO/WHO just announced that this consultation will occur during 2007 and early 2008.

In August 2006, FDA launched its "Lettuce and Leafy Greens Initiative," which assesses practices and conditions at select farms and facilities in California, in collaboration with California's Department of Health Services and its Department of Food and Agriculture. FDA launched a similar Tomato Safety Initiative in Virginia and Florida on June 12 of this year. We will continue to work with Federal, state, local and international food safety partners and with industry to develop guidance, conduct research, develop educational outreach materials, and initiate other commodity- or region-specific programs to enhance the safety of fresh produce.

In response to the contamination of pet food and animal feed, FDA has worked closely with a broad partnership that includes scientists in government, industry, and academia and with 50 state departments of agriculture, health authorities, veterinarians**,** and the Association of American Feed Control Officials. We are utilizing data from Banfield Pet Hospital (a nationwide network of veterinary hospitals), the Veterinary Information Network, Poison Control Centers, universities, and other organizations to assess the extent of the outbreak of cat and dog illnesses and deaths.

FDA scientists recently worked with the Food Safety and Inspection Service of USDA, CDC, the Environmental Protection Agency (EPA), and the Department of Homeland Security (DHS) to develop a risk assessment to evaluate the risk to human health from consuming pork, chicken, fish, and eggs from animals inadvertently fed animal feed containing pet food that contained melamine and melamine-related compounds. The assessment found that this consumption is very unlikely to pose a human health risk. The risk assessment is an important new science-based component of the continuing federal joint investigation into imported wheat gluten and rice protein concentrate from China that contained melamine and melamine-related compounds. On June 14 the Science Board, which is an FDA Advisory Committee, met to review and discuss the risk assessment and its subsequent peer-review. The Board concurred with the findings in the report, including the low probability of risk to humans, analysis of risk to the food supply and methods used in the assessments. The Science Board also made recommendations for additional research for future assessments.

In addition, the FDA/USDA Food Emergency Response Network (FERN) has continued to grow and enhance the nation's food testing capacity. FERN is a network of Federal, state, and local laboratories capable of testing food samples for microbiological, chemical, and radiological threat agents. This partnership provides essential analytical expertise and surge capacity during emergencies. The FERN network proved to be a critical asset in the *E. coli* O157:H7 outbreak associated with fresh spinach. FERN analysts worked closely with CDC's Laboratory Response Network personnel to harmonize and approve a modified FERN method for detecting *E. coli* O157:H7 in spinach. This method allowed for substantially improved testing of spinach samples as it allowed for the detection of *E. coli* O157:H7 at lower levels.

FDA is also a significant participant in international food safety standards organizations such as the Codex Alimentarius, assisting in the development of international standards that reflect the level of food safety protection equivalent to domestic standards. These international standards are vital to the safety of foods imported into the U.S. FDA also provides foreign countries with training in all aspects of food production, technology, transportation and consumer advice.

Recently, concerns have been elevated about the quality and safety of products imported from China. HHS and FDA are currently planning negotiation of a Memorandum of Understanding (MoU) with relevant regulators in China to address food and feed safety as well as a separate MoU on medical product safety.

Office of Regulatory Affairs's (ORA's) Transformation: Improving Risk-Based Targeting of Inspection Resources

ORA is the lead organization within FDA responsible for enforcing FDA's public health laws and regulations. ORA supports FDA's public health mission by maximizing compliance of FDA-regulated products and minimizing risks associated with those products. ORA's activities include conducting inspections, collecting and analyzing samples, initiating investigations, overseeing recalls, taking enforcement actions, and monitoring the entry of regulated products at our nation's borders.

Today ORA faces significant challenges in carrying out its public health mission. In the 21st Century, we are confronted with increasingly complex products manufactured through highly technical processes and requiring stringent controls. These products are no longer produced

exclusively in America; there is an increasing volume of products from overseas, often from countries with emerging regulatory systems. New food pathogens and counterterrorism responsibilities place an additional burden on our traditional regulatory process. And the challenges arising from these changes promise to become even more complex and difficult to address.

ORA's field organizational structure and the methods and tools it employs date back 40 years – to a time that pre-dates the tissue transplant industry, pre-dates computerized implantable medical devices such as defibrillators, and pre-dates the year-round availability of fresh produce and other products from all over the world. ORA is at an historic crossroads – with unprecedented challenges and opportunities before it. The volume and complexity of our work has never been greater. In order to continue to meet today's challenges successfully and to respond swiftly and effectively to new threats and public health emergencies, we must adapt and become a more dynamic, flexible, and responsive organization. This means transforming ORA, adapting and improving its tools, methods and technologies to meet the expanding and ever-changing aspects of its mission to protect the health of the American people.

Enhancing risk-based approaches, as a systematic means of prioritizing our work to maximize public health impact, is a key element to meeting the challenges of today and tomorrow. ORA, together with CFSAN, have made great strides in focusing our food safety work where it has the greatest impact on protecting the public. But there continue to be significant opportunities to enhance our risk-based approaches. We must develop more flexible, mobile and adaptable approaches to getting the job done, including approaches that improve our efforts to target high risk products to protect the American public, and approaches that leverage our resources through

enhanced collaboration with domestic and foreign regulatory counterparts. New tools must include the use of risk management analyses to refine and focus inspection strategies; increasing data mining for more effective monitoring of imports; increasing the number of foreign establishment inspections; updating the capabilities and efficiency of our regulatory laboratories; and expanding partnerships with states and other regulatory bodies to augment existing inspection capabilities.

Our transformation proposal calls for streamlining management in the field. Doing this will reduce management and overhead costs, while allowing us to support the same, or even greater, number of inspections and to invest in assuring that our employees have the skills, tools and training they need to do their jobs. Our proposal will significantly enhance our capability to assess and rank risks in order to improve the targeting of our inspection, enforcement, and analytical resources. The need to increase the use of risk-based approaches is especially acute for imports. And because responding to public health emergencies will continue to be a priority for ORA, our plan will enhance our capacity to work with state and Federal partners to better manage and coordinate FDA's emergency response activities. Our plan will multiply the impact of all of our resources by enhancing partnerships with our regulatory counterparts and stakeholders, both domestically and abroad. In 2003, FDA worked with state counterparts to create the California Food Emergency Response Team (CALFERT), which includes inspectors and analysts from ORA's San Francisco and Los Angles District Offices and the California Department of Health Services' Food and Drug Branch. Because this model was so successful during the *E. coli* O157:H7 outbreak associated with fresh spinach, we are pursuing ways to expand this concept.

ORA's transformation proposal, if implemented, will improve our analytical capacity and capability by creating from our existing thirteen field laboratories a strengthened, enhanced network of six centrally managed state-of-the-art regulatory laboratories. Because the Committee has expressed particular interest in the laboratory consolidation, I would like to provide some additional information about this component of our transformation.

As I have already stated, ORA must have well-equipped and well-maintained state-of-the-art regulatory laboratories that can quickly and effectively analyze a high volume of regulatory samples and that can adapt swiftly to emerging threats and challenges. With rapid package delivery services widely available, these laboratories do not need to be near every sample collection site. Indeed, given that we collect samples in literally thousands of locations, it is not possible to have a laboratory in close proximity to every collection site. FDA's mobile labs have been an extremely valuable resource to this Agency, and have proven their effectiveness in responding to emergencies. They complement FDA's traditional laboratories and provide flexibility for emergency response.

The six enhanced laboratories are dispersed geographically throughout the country. They have sufficient space to accommodate all of our analysts and equipment, including those from the seven labs from which people, work, and equipment will be transferred. Currently, FDA pays costs associated with approximately forty percent more laboratory space than is needed to conduct all of the laboratory work performed in support of all of FDA's field programs and activities. In some cases, the existing laboratories are housed in older buildings that require higher-than-average maintenance and repair costs. Reducing the number of laboratories for which FDA pays utilities, maintenance, and security costs will enable us to invest in up-to-date

equipment and the maintenance of that equipment; high efficiency sample throughput technologies to increase analytical speed and capacity; development of new methods to detect emerging threats; better training for our laboratory analysts; and the development of rapid screening methodologies for use at ports of entry and elsewhere. Consolidating our work into six laboratories whose capacity will meet and even exceed the capacity of FDA's 13 existing field laboratories will strengthen and increase ORA's analytical capabilities to meet the challenges of the 21st Century.

FDA values its dedicated workforce, and every analyst from a closing laboratory will be offered a job in the laboratory to which his or her work is transferred. Although we realize that some employees will choose not to relocate, there may be opportunities for them to compete for positions in the same or nearby locations, in other high priority and currently under-resourced program areas such as inspections and import review work. The laboratory consolidation will be implemented over a two-year period, and we are now developing detailed implementation plans designed to limit any adverse impact on our analytical work. These plans will allow us to adjust for changes in workflow and laboratory efficiency as the process moves forward so that we will be able to meet our obligations and continue laboratory operations in a seamless manner.

CONCLUSION

FDA is working hard to ensure the safety and security of food, in collaboration with our Federal, state, local, and international food safety partners, and with consumers, industry, and academia. As a result of this effective collaboration, the American food supply continues to be among the safest in the world. Although we have made progress, much remains to be done. The recent

incidents of contaminated food and animal feed demonstrate the challenges we face and the need to move toward a food safety and security system that is even more proactive and strategic, with a field force that is trained and equipped to focus on the challenges of today and tomorrow.

Mr. Chairman, as a firm believer in continuous improvement, I can assure you that FDA will be up to the challenge. I appreciate the opportunity to discuss FDA's food safety activities and the ORA Transformation Initiative today. My colleagues and I would be happy to answer any questions.